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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/499,693	02/08/2000	Insu Lee	00120/P-4858	1622

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EXAMINER
WELLS, LAUREN Q

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 05/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/499,693	LEE ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Lauren Q Wells	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 24 November 2003.

2a) This action is FINAL.      2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 26-45 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 26-45 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>11/24/03</u> .	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
	6) <input type="checkbox"/> Other: _____

### **DETAILED ACTION**

Claims 26-45 are pending. The Amendment filed 11/24/03, amended claims 26 and 34. The Amendment of 11/24/03 further states that claim 42 is “currently amended”, but this claim contains no amendment.

Applicant’s amendment of 11/24/03 to claim 26 is sufficient to overcome the 35 USC 112 rejection over this claim.

#### ***103 Rejection Maintained***

The rejection of claims 26, 34, 38 and 42 under 35 U.S.C. 103(a) as being unpatentable over Leach (5,612,074) is MAINTAINED for the reasons set forth in the Office Action mailed 6/24/03, and those found below.

The rejection of claims 27, 31, 35, 39 and 43 under 35 U.S.C. 103(a) as being unpatentable over Leach (5,612,074), as applied to claims 26, 34, 38 and 42 above, and further in view of Erasmus et al. (5,656,312) and Hunter et al. (4,863,753) is MAINTAINED for the reasons set forth in the Office Action mailed 6/24/03, and those found below.

The rejection of claims 28, 30, 32, 36, 40 and 44 under 35 U.S.C. 103(a) as being unpatentable over Leach (5,612,074), as applied to claims 26, 34, 38 and 42 above, and further in view of Igarashi (6,159,507) is MAINTAINED for the reasons set forth in the Office Action mailed 6/24/03, and those found below.

The rejection of claims 29, 33, 37, 41 and 45 under 35 U.S.C. 103(a) as being unpatentable over Leach (5,612,074) in view of Eramus et al. and Hunter et al., as applied to claims 26, 27, 31, 34, 35, 38, 39, 42 and 43 above, and further in view of Igarashi (6,159,507) is

MAINTAINED for the reasons set forth in the Office Action mailed 6/24/03, and those found below.

Applicant argues, "Leach teaches that the linoleic/linolenic ratio of the oil seeds in the dry ingredients and the vegetable oil in the liquid ingredients should be in a 3:1 ratio. This is in contradistinction to a teaching of an end product having a linoleic/linolenic ratio of 3:1, since it is clear that the resulting food bar in Leach. . . This argument is not persuasive. Leach teaches his food bar, a composition, as having a ratio of linoleic to linolenic of 3:1. It is respectfully pointed out that the instant claims are directed to a products comprising ingredients in certain ratios. Leach teaches such a product in such a ratio. The Examiner respectfully points out that the abstract of Leach specifically states, "The food bar contains about 35% by weight of complex carbohydrates, about 17% by weight of simple carbohydrates, with polyunsaturated linoleic acid present in a ratio of about 3:1 by weight to superunsaturated alphalinolenic acid". Thus, there is no contradistinction. Leach teaches a composition comprising linoleic acid to linolenic acid in a ratio encompassed by this instant claims.

Applicant argues, "As noted in Point 8 and 9 of Dr. Lee's Declaration, addition of an amount of a linoleic and/or alpha-linolenic acid containing ingredient that moves the linoleic/alpha-linolenic weight ratio outside of 0.05-7.5 is excluded. . . The Examiner's attention is directed to Point 8 of Dr. Lee's Declaration where it is discussed that at the weight ratio of linoleic fatty acid to alpha-linolenic fatty acid of 0.05 to 7.5, DHA is synthesized most efficiently, particularly in the brain. As further detailed in Point 8 of Dr. Lee's Declaration, addition of ingredients that alter the linoleic fatty acid to alpha-linolenic fatty acid weight ratio outside of this weight ratio fail to produce the increase in cognitive and learning faculty and in

the memory". This argument is not persuasive. First, the Examiner respectfully directs Applicant to the claims, which recite a composition consisting essentially of linoleic and alpha-linolenic fatty acid, wherein the composition further contains flaxseed oil. Dependent claims 28 recite the composition further comprising rapeseed oil and perilla oil. Thus, the instant independent and dependent claims contain both open (containing and comprising) and partially closed (consisting essentially of) language. In giving the claims their broadest reasonable interpretation in light of the specification, the instant claims are being examined as open-ended. Furthermore, it is respectfully pointed out that flaxseed oil, rapeseed oil, and perilla oil all contain linoleic and alpha-linolenic fatty acids. Thus, the addition of these oils to a composition comprising linoleic fatty acid and alpha-linolenic acid will materially affect the ratio of linoleic to linolenic acid. For this reason alone the instant declaration is not persuasive. Additionally, it is respectfully pointed out that the instant declaration contains statements and no data. In Point 8, the declaration states, "Addition of ingredients that alter the composition's linoleic fatty acid to alpha-linolenic fatty acid ratio to be outside of this range fail to produce this increase in cognitive and learning faculty and the memory". However, the declaration provides no scientific rationale or data to substantiate this point.

Furthermore in Point 9 of the declaration it states, "it is my professional opinion that the introduction of additional steps or components would materially change the characteristics of applicant's invention". This argument is not persuasive. First, it is respectfully pointed out that Applicant is actually stating that it is his opinion and that it is not fact. Second, it is respectfully pointed out that Applicant has provided no evidence or scientific rationale that additional ingredients would materially affect the instant invention. Furthermore, as stated above, the

combination of open ended and partially closed language in the instant claims, does not support a declaration attempting to establish the metes and bounds of the recitation “consisting essentially of”.

Applicant argues, “As discussed in point 7 . . . Leach discloses numerous ingredients in the food bar that materially effect the ratio of linoleic/alpha-linolenic fatty acid. For example, soy, oatmeal, cornmeal, wheat germ, barley, rye. . . and coriander seeds are each disclosed as ingredients for the food bar. Each of these is a source of linoleic and/or alpha-linolenic fatty acid and addition of any one or more would materially alter the ratio of these fatty acids”. This argument is not persuasive. First, it is respectfully pointed out it is well-established that consideration of a reference is not limited to the preferred embodiments or working examples, but extends to the entire disclosure for what it fairly teaches, when viewed in light of the admitted knowledge in the art, to person of ordinary skill in the art. In re Boe, 355 F.2d 961, 148 USPQ 507, 510 (CCPA 1966); In re Lamberti, 545 F.2d 747, 750, 192 USPQ 279, 280 (CCPA 1976); In re Fracalossi, 681 F.2d 792, 794, 215 USPQ 569, 570 (CCPA 1982); In re Kaslow, 707 F.2d 1366, 1374, 217 USPQ 1089, 1095 (Fed. Cir. 1983). The Examiner respectfully directs Applicant to the abstract of Leach, which specifically states, “The food bar contains about 35% by weight of complex carbohydrates, about 17% by weight of simple carbohydrates, with polyunsaturated linoleic acid present in a ratio of about 3:1 by weight to superunsaturated alpha linolenic acid”. Second, even if Leach did not teach this ratio, it is respectfully pointed out that it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Applicant argues, “no consideration of the final linoleic and/or alpha linolenic acid weight of the Leach food bar is given. The teaching in Leach with respect to linoleic/alpha-linolenic acid ratio is limited to a teaching of a 3:1 ratio for the oil seeds of the dry ingredients and the vegetable oil of the liquid ingredients”. This argument is not persuasive. Again, Applicant is arguing against the exemplifications, when the reference was considered as a whole for what it teaches and makes obvious to one of ordinary skill in the art. See above paragraphs.

After reading the instant specification, it appears to the Examiner that Applicant's invention is actually a composition comprising flaxseed oil (and optionally rapeseed and perilla oil), wherein the linoleic to alpha-linolenic weight ratio is 0.05-7.5. If this is actually Applicant's invention, the Examiner respectfully suggests that Applicant amend the claims to recite such an invention. Furthermore, as discussed in the interview, if this is the case, it will be Applicant's burden to show that the flaxseed oil itself does not contain a ratio of linoleic to linolenic acid, as recited in the instant claims, since a compound and its properties are inseparable.

*Conclusion*

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

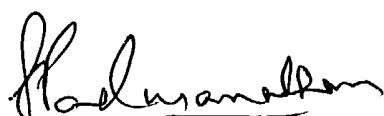
CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lauren Q Wells whose telephone number is 571-272-0634. The examiner can normally be reached on M&R (5:30-4).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

lqw



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